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Proposed Re-evaluation Decision PRVD2014-02

Dimethoxane

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Overview

What Is the Proposed Re-evaluation Decision?

After a re-evaluation of the material preservative dimethoxane, Health Canada's Pest Management Regulatory Agency (PMRA), under the authority of the *Pest Control Products Act* and Regulations, is proposing continued registration of products containing dimethoxane for sale and use in Canada.

An evaluation of available scientific information found that products containing dimethoxane do not present unacceptable risks to human health or the environment when used according to the revised label directions. As a condition of the continued registration of dimethoxane uses, new risk-reduction measures are proposed to be included on the label of the product. Additional data are also required as a result of this re-evaluation.

This proposal affects the end-use products containing dimethoxane registered in Canada. Once the final re-evaluation decision is made, the registrants will be instructed on how to address any new requirements.

This Proposed Re-evaluation Decision is a consultation document[1] that summarizes the science evaluation for dimethoxane and presents the reasons for the proposed re-evaluation decision. It also proposes additional risk-reduction measures to further protect human health and environment.

The information is presented in two parts. The Overview describes the regulatory process and key points of the evaluation, while the Science Evaluation provides detailed technical information on the assessment of dimethoxane.

The PMRA will accept written comments on this proposal up to 45 days from the date of publication of this document. Please forward all comments to Publications (please see contact information indicated on the cover page of this document).

What Does Health Canada Consider When Making a Re-evaluation Decision?

The PMRA's pesticide re-evaluation program considers potential risks, as well as value, of pesticide products to ensure they meet modern standards established to protect human health and the environment. Regulatory Directive DIR2012-02, *Re-evaluation Program Cyclical Re-evaluation*, presents the details of the cyclical re-evaluation approach.

Dimethoxane is registered in the United States as a material preservative. The United States Environmental Protection Agency (USEPA) completed a Reregistration Eligibility Decision in 1996. In June 2011, the USEPA published the final workplan for dimethoxane. The Canadian

[1] "Consultation statement" as required by subsection 28(2) of the *Pest Control Products Act*.

use pattern is encompassed by the American use pattern, and hence, the PMRA used the USEPA documents as a basis for the re-evaluation of dimethoxane.

For more details on the information presented in this Overview, please refer to the Science Evaluation of this consultation document.

What is Dimethoxane?

Dimethoxane is a material preservative that is used in adhesives, dyestuffs, emulsions, gums, inks, latex, polyvinyl acetate, silicone, textile auxiliaries and thickeners. It can be either applied by the open-pouring method or via a closed delivery system.

Health Considerations

Can Approved Uses of Dimethoxane Affect Human Health?

Dimethoxane is unlikely to affect your health when used according to the revised label directions.

People could be exposed to dimethoxane by working as a mixer/loader in industrial settings and through contact with products containing materials treated with dimethoxane. The PMRA considers two key factors when assessing health risks: the levels at which no health effects occur and the levels to which people may be exposed. The dose levels used to assess risks are established to protect the most sensitive human population (for example, children and nursing mothers). Only uses for which exposure is well below levels that cause no effects in animal testing are considered acceptable for continued registration.

The PMRA concluded that the registration of dimethoxane is acceptable provided that additional mitigation measures are implemented (Appendix IV).

Environmental Considerations

What Happens When Dimethoxane Is Introduced Into the Environment?

Dimethoxane is unlikely to affect non-target organisms when used according to the revised label directions.

Given the currently registered use pattern under the *Pest Control Products Act*, and the environmental fate data indicating a rapid degradation of dimethoxane in water, the potential for environmental exposure is considered to be minimal. The PMRA concluded that dimethoxane is unlikely to cause harm to the environment. Standard environmental advisory label statements to minimize surface water contamination are proposed.

Measures to Minimize Risk

Labels of registered pesticide products include specific instructions for use. Directions include risk-reduction measures to protect human health and the environment. These directions must be followed by law. As a result of the re-evaluation of dimethoxane, the PMRA is proposing further risk-reduction measures for product labels (Appendix IV).

Human Health

- A statement prohibiting the use of this active ingredient in the production of materials that will come into contact with food
- A hazard label statement addressing skin sensitization potential
- Personal protective equipment to protect workers in industrial settings

Environment

- Standard environmental statements to minimize surface water contamination

A submission to implement label revisions will be required within 90 days of finalization of the re-evaluation decision.

What Additional Scientific Information Is Required?

Data are required as a condition of continued registration under Section 12 of the *Pest Control Products Act*. The registrant of this active ingredient must provide these data or an acceptable scientific rationale to the PMRA within the timeline specified in the decision letter. Appendix I lists all data requirements.

Next Steps

Before making a final re-evaluation decision on dimethoxane, the PMRA will consider all comments received from the public in response to this consultation document. The PMRA will then publish a Re-evaluation Decision[2] that will include the decision, the reasons for it, a summary of comments received on the proposed decision and the PMRA's response to these comments.

[2] "Decision statement" as required by subsection 28(5) of the *Pest Control Products Act*.

Science Evaluation

1.0 Introduction

Dimethoxane is a material preservative that is used in adhesives, dyestuffs, emulsions, gums, inks, latex, polyvinyl acetate, silicone, textile auxiliaries and thickeners.

Following the re-evaluation announcement for dimethoxane, the registrant of the technical grade active ingredient in Canada indicated that they intended to provide continued support for all uses included on the label of commercial class end-use product in Canada.

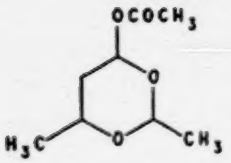
Currently registered products containing dimethoxane are listed in Appendix II. All current uses are being supported by the registrant and were, therefore, considered in the re-evaluation of dimethoxane.

The assessment for dimethoxane was based on the available assessments conducted by the United States Environmental Protection Agency (USEPA). Occupational and residential exposure and risk assessments were conducted by the PMRA. The USEPA Reregistration Eligibility Decision document for dimethoxane, can be found at http://www.epa.gov/pesticides/reregistration/status.htm. The 2010 USEPA Registration document for dimethoxane is available at: www.regulations.org, docket ID EPA-HQ-OPP-2010-0686.

2.0 The Technical Grade Active Ingredient, Its Properties

2.1 Identity of the Technical Grade Active Ingredient

Common name		Dimethoxane
Function		Material Preservative
Chemical Family		Dioxane
Chemical name		
	1 International Union of Pure and Applied Chemistry (IUPAC)	6-Acetoxy-2,4-dimethyl-m-dioxane
	2 Chemical Abstracts Service (CAS)	1,3-Dioxan-4-ol, 2,6-dimethyl-, 4-acetate
CAS Registry Number		828-00-2

Molecular Formula	$C_8H_{14}O_4$
Structural Formula	
Molecular Weight	174.19
Purity of the Technical Grade Active Ingredient	92.0%
Registration Number	27039

Based on the manufacturing process used, impurities of human health or environmental concern as identified in the Canada Gazette, Part II, Vol. 142, No. 13, SI/2008-67 (2008-06-25), including TSMP Track 1 substances, are not expected to be present in the product.

2.2 Physical and Chemical Properties of the Technical Grade Active Ingredient

Property	Result	Interpretation
Vapour pressure at 20°C	29.1 Pa	High volatility
Ultraviolet (UV) / visible spectrum	Absorbance observed up to 400 nm	Potential for phototransformation
Solubility in water	100%	Very soluble in water
n-Octanol/water partition coefficient	Not applicable as dimethoxane hydrolyzes in water	Bioaccumulation is unlikely
Dissociation constant	Not applicable as dimethoxane does not contain base or acid functionalities	-

2.3 Description of Registered Dimethoxane Uses

Dimethoxane is a material preservative that is used in adhesives, dyestuffs, emulsions, gums, inks, latex, polyvinyl acetate, silicone, textile auxiliaries and thickeners. Dimethoxane is applied by open-pouring method and by closed delivery system with an application rate of up to 0.2% by weight. The end-use product is formulated as a solution.

3.0 Human Health

Toxicology studies in laboratory animals describe potential health effects resulting from various levels of exposure to a chemical and identify dose levels at which no effects are observed. Unless there is evidence to the contrary, it is assumed that effects observed in animals are relevant to humans and that humans are more sensitive to effects of a chemical than the most sensitive animal species.

Exposure to dimethoxane may occur through working as a mixer/loader and/or while handling treated products.

When assessing health risks, the PMRA considers two key factors: the levels at which no health effects occur and the levels to which people may be exposed. The dose levels used to assess risks are established to protect the most sensitive human population (for example, children and nursing mothers).

3.1 Toxicology Summary

Dimethoxane was found to be of low acute toxicity via oral, dermal and inhalation routes of exposure in rats. In a primary eye irritation study in rabbits, a mild transient ocular irritation was observed. In a primary rabbit dermal irritation study, slight erythema, with irritation clearing in all but one animal by 48 hours was reported. In a dermal sensitization study conducted with guinea pigs, dimethoxane was shown to be a strong sensitizer.

In a 90-day dermal toxicity study in rat, the dermal NOAEL (no observed adverse effect level) of 100 mg/kg bw/day was set based on reduced body weight gains in males and an increased incidence of hepatic changes (including necrosis, inflammation, and hemorrhage) in females at 300 mg/kg bw/day. This endpoint of 100 mg/kg bw/day was selected for all dermal durations.

In subchronic studies conducted by the U.S. National Toxicology Program (NTP), effects (such as ulceration, inflammation, and acanthosis) were observed. Deaths occurred in rats and in male mice that received 2,000 mg/kg bw/day in a 16 day oral gavage study.

In a 15-month rat and mice gavage study, the NOAEL of 125 mg/kg bw/day was set based on effects on the forestomach observed in male rat at 125 mg/kg bw/day, and in female rats at 250 mg/kg bw/day. This NOAEL was selected for assessment of short- and intermediate- term durations incidental oral risks.

In a 2-year NTP cancer study, there was equivocal evidence of carcinogenic activity of dimethoxane for male mice, as indicated by an increased incidence of forestomach neoplasms. However, there was no evidence of dimethoxane carcinogenicity in female mice or in male or female rats.

No evidence of developmental toxicity was observed in a gavage developmental study in rats. The developmental NOAEL was considered to be 900 mg/kg bw/day. The maternal NOAEL was

determined to be 300 mg/kg bw/day, and the maternal LOAEL was determined to be 900 mg/kg bw/day, based on reduced body weight gain and food consumption, and excessive salivation.

Dimethoxane was negative in both micronucleus and unscheduled DNA Synthesis tests. Dimethoxane was found to be non-mutagenic in the Ames Salmonella assay. The active ingredient was found to be negative in the rat hepatocyte unscheduled DNA synthesis test. It was clastogenic in Chinese hamster ovary cells with activation, but negative without activation.

The toxicology endpoints selected by the USEPA in 2010 for use in human risk assessment are listed in Appendix III.

The PMRA is proposing the hazard statement regarding skin sensitization potential on the product label. Furthermore, additional data are required to determine whether dimethoxane is likely to cause sensitization as a result of exposure to finished treated products. Appendix I lists all data requirements.

3.2 Occupational Exposure and Risk Assessment

Exposure to dimethoxane may occur while mixing/loading the pesticide in industrial settings and through contact with products treated with dimethoxane.

When assessing health risks, the PMRA considers two key factors: the levels at which no health effects occur and the levels to which people may be exposed. The dose levels used to assess risks are established to protect the most sensitive human population (for example, children and nursing mothers).

3.2.1 Occupational Exposure

Occupational risk is estimated by comparing potential exposures with the most relevant endpoint from toxicology studies being used to calculate a margin of exposure (MOE). This is compared to a target MOE incorporating uncertainty factors protective of the most sensitive subpopulation. If the calculated MOE is less than the target MOE, it does not necessarily mean that exposure will result in adverse effects, but mitigation measures to reduce exposure would be required.

3.2.1.1 Chemical Handler Exposure and Risk

Based on the current use pattern, exposure to dimethoxane for workers is expected to be via dermal and inhalation routes for open pour and for a closed system. Exposure duration is expected to be intermediate- to long-term.

Because chemical-specific exposure data are not available for dimethoxane, the PMRA used dermal exposure estimates derived from the Chemical Manufacturers Association Antimicrobial Exposure Study to assess risks for chemical handlers. Using the NOAEL of 100 mg/kg bw/day from a rat dermal study, the resulting dermal MOEs were 967 for open pour and 3731 for closed system. In the absence of an inhalation endpoint as a chemical-specific inhalation study is not available, the lowest oral endpoint of 125 mg/kg bw/day was used and 100% inhalation

absorption was assumed. The resulting MOEs were 125,000 for open pour and 39,063 for a closed system. The MOEs were above the target MOE of 100, indicating there is no risk of concern.

Based on the personal protective equipment used by workers in the Chemical Manufacturers Association study, the PMRA proposes a long-sleeved shirt, long pants, and chemical resistant gloves for workers during handling, clean-up, and repair activities.

3.2.1.2 Postapplication Exposure and Risk

Postapplication exposure to dimethoxane is expected to be via dermal and inhalation routes.

3.2.1.2.1 Postapplication Exposure and Risk for Professional Painters

There is the potential for exposure to products that contain materials that are treated with dimethoxane. For example, latex emulsions treated with dimethoxane may be used in the production of latex-based paint. The percentage of dimethoxane in the finished product was assumed to be the maximum Canadian application rate for dimethoxane in latex emulsion (0.2%). Dermal and inhalation exposure estimates for professional painters were generated using the Pesticide Handlers Exposure Database, and assuming the use of a single layer of clothing without gloves.

Using the NOAEL of 100 mg/kg bw/day from a rat dermal study, the estimated dermal MOEs were 220 for using airless sprayer and 467 for paint brush. Using the lowest oral endpoint (125 mg/kg bw/day) and 100% inhalation absorption, the estimated inhalation MOEs were 21,735 for airless sprayer and 314,861 for paint brush. The MOEs were above the target MOE of 100, indicating that the postapplication dermal and inhalation risk for workers exposure to dimethoxane in finished products is not of concern. Therefore, no mitigation measures are proposed.

3.3 Non-Occupational Exposure and Risk Assessment

3.3.1 Dietary Exposure and Risk

Dimethoxane is not registered in Canada for food or feed uses. Therefore, a dietary risk assessment was not conducted. Based on the currently registered use pattern, the PMRA proposes the requirement of a statement prohibiting the use of dimethoxane in the production of materials that will come into contact with food.

3.3.2 Residential Exposure and Risk

Currently, there are no products containing dimethoxane intended for residential use, therefore, exposures in residential settings would be limited to exposure to dimethoxane residues in finished products, for example, in latex paint and textiles.

3.3.2.1 Postapplication Exposure and Risk for Homeowners Applying Latex Paint

As discussed in Section 3.2.1.2.1, the percentage of dimethoxane in the final latex paint formulation was assumed to be the maximum Canadian application rate in latex emulsion (0.2%). Dermal and inhalation exposure estimates for a homeowner wearing short pants, short-sleeved shirt and without gloves were generated using the Pesticide Handlers Exposure Database, and assuming a paint volume of 56.8 L for airless sprayer and 7.6 L for the paintbrush scenario [USEPA Residential Standard Operating Procedures (USEPA Residential SOP, 1997)].

Using the NOAEL of 100 mg/kg bw/day from a rat dermal study, the estimated dermal exposure MOEs were 338 for using airless sprayer, and 897 for using paint brush. Using the lowest oral endpoint (125 mg/kg bw/day) and 100% inhalation absorption, the estimated inhalation MOEs were 71,839 for airless sprayer and 776,398 for paint brush. They were above the target MOE of 100, indicating that the residential postapplication dermal and inhalation exposure to dimethoxane in finished products is not of concern. Therefore, no mitigation measures are proposed.

3.3.2.2 Incidental Oral Exposure of Children from Ingestion of Paint Chips

Exposure for children (6–18 months old) eating paint chips were estimated according to the USEPA Residential SOP (1997). Since the final concentration of dimethoxane in the finished paint products is unknown, the maximum application rate approved for use in the preservation of latex emulsion (0.2%) was assumed for risk assessment.

The estimated oral MOE is 78,125, and above the target MOE of 100, indicating that the risk is not of concern.

Since there is no risk concern for residential exposure scenarios estimated, no mitigations are proposed

3.4 Aggregate Exposure and Risk

Aggregate risk combines the different routes of exposure to dimethoxane (for example, from dietary and residential exposures). Since dimethoxane is not registered for food use, an aggregate risk assessment was not conducted.

3.5 Cumulative Exposure and Risk

The USEPA has not determined whether dimethoxane has a common mechanism of toxicity with other substances or whether it shares a toxic metabolite produced by other substances. A cumulative risk assessment was not required at this time.

4.0 Environment

4.1 Environment Fate

The major route of degradation was abiotic hydrolysis aided by microbial mediated degradation. Dimethoxane is highly unstable in water with over 50% of the compound hydrolyzed in 2 hours. Dimethoxane is appearing to react with water to form acetic acid and a transient intermediate, dioxinol. The dioxinol then breaks down into acetaldehyde and aldol (aldehyde + alcohol dimer). The breakdown into acetic acid and dioxinol is completed in 14 hours.

4.2 Environmental Exposure and Risk Assessment

The USEPA reported that dimethoxane was slightly toxic to practically nontoxic to avian species on an acute oral and subacute dietary exposure basis; it was slightly toxic to both cold and warm water fish; and it was slightly toxic to aquatic invertebrates; it was toxic to fresh water algae at 3.4 ppm.

Given the currently registered use pattern under the *Pest Control Products Act*, the PMRA concluded that dimethoxane is unlikely to cause harm to the environment. Therefore, no additional environmental data requirement is proposed at this time.

Based on current PMRA general practices, standard environmental label statements to minimize surface water contamination are proposed to be included on the commercial end-use product label. The proposed label amendments are listed in Appendix IV.

5.0 Value

Dimethoxane is an important preservative agent in the preservation of numerous types of emulsions and water-based industrial processes. It provides an additional active ingredient to those currently registered as material preservatives.

6.0 Pest Control Product Policy Considerations

6.1 Toxic Substances Management Policy Considerations

The Toxic Substances Management Policy (TSMP) is a federal government policy developed to provide direction on the management of substances of concern that are released into the environment. The TSMP calls for the virtual elimination of Track 1 substances [those that meet all four criteria outlined in the policy, for example, persistent (in air, soil, water and/or sediment), bioaccumulative, primarily a result of human activity and toxic as defined by the *Canadian Environmental Protection Act*].

Although not all environmental fate data are available, due to its high instability in water, dimethoxane does not meet all TSMP Track 1 criteria.

6.2 Contaminants and Formulants of Health or Environmental Concern

During the re-evaluation of dimethoxane, contaminants in the technical are compared against the List of Pest Control Product Formulants and Contaminants of Health or Environmental Concern maintained in the Canada Gazette. The list is used as described in the PMRA Notice of Intent NOI2005-01 and is based on existing policies and regulations including DIR99-03 and DIR2006-02, and taking into consideration the Ozone-depleting Substance Regulations, 1998, of the *Canadian Environmental Protection Act* (substances designated under the Montreal Protocol). The PMRA has reached the following conclusion:

Technical grade dimethoxane does not contain any contaminants of health or environmental concern identified in the Canada Gazette, Part II, Vol. 142, No. 13, SI/2008-67 (2008-06-25).

The use of formulants in registered pest control products is assessed on an ongoing basis through PMRA formulant initiatives and Regulatory Directive DIR2006-02.

7.0 Incident Reports

Starting 26 April 2007, registrants are required by law to report incidents, including adverse effects to health and the environment, to the PMRA within a set time frame.

There were no incident reports submitted for dimethoxane as of 3 July 2013.

8.0 Organization for Economic Co-operation and Development Status of Dimethoxane

Canada is part of the Organisation for Economic Co-operation and Development (OECD), which groups 34 member countries and provides governments with a setting in which to discuss, develop and perfect economic and social policies.

As part of the re-evaluation of an active ingredient, the PMRA takes into consideration recent developments and new information on the status of an active ingredient in other jurisdictions, including OECD member countries. In particular, decisions by an OECD member to prohibit all uses of an active ingredient for health or environmental reasons are considered for relevance to the Canadian situation.

Dimethoxane is currently acceptable for use in several OECD countries, including the United States. No decision by an OECD member country to prohibit all uses of dimethoxane for health or environmental reasons has been identified.

The European Commission implemented decisions in 2008 and 2010 prohibiting the use of dimethoxane in certain biocidal product types. However, the European Commission decision was due to withdrawal or incomplete support for the chemical by the registrant in the European review program and was not as a result of a health or environmental concern.

9.0 Proposed Re-evaluation Decision

The PMRA is proposing that products containing dimethoxane for sale and use in Canada are acceptable for continued registration with the implementation of the proposed label amendments (Appendix IV). These amendments are required to further protect human health and the environment. Additional data are also required under Section 12 of the *Pest Control Products Act* (Appendix I).

10.0 Supporting Documentation

PMRA documents, such as Regulatory Directive DIR2012-02, *Re-evaluation Program Cyclical Re-evaluation*, and DACO tables can be found on the Pesticides and Pest Management portion of Health Canada's website at healthcanada.gc.ca/pmra. PMRA documents are also available through the Pest Management Information Service. Phone: 1-800-267-6315 within Canada or 1-613-736-3799 outside Canada (long distance charges apply); fax: 613-736-3798; e-mail: pmra.infoserv@hc-sc.gc.ca.

The federal TSMP is available through Environment Canada's website at www.ec.gc.ca/toxics.

The USEPA Reregistration Eligibility Decision document for dimethoxane is available at http://www.epa.gov/pesticides/reregistration/status.htm.

The USEPA Registration document for dimethoxane is available at: www.regulations.org, docket ID EPA-HQ-OPP-2010-0686.

List of Abbreviations

°C	degree(s) Celsius
bw	body weight
CAS	Chemical Abstracts Service
DACO	data code
DNA	deoxiribonucleic acid
g	gram(s)
IUPAC	International Union of Pure and Applied Chemistry
Kg	kilogram(s)
L	litre(s)
mg	milligram(s)
MOE	margin of exposure
NOAEL	no observed adverse effect level
nm	nanometre(s)
NTP	U.S. National Toxicology Program
OECD	Organisation for Economic Co-operation and Development
Pa	Pascal
PMRA	Pest Management Regulatory Agency
ppm	parts per million
PRVD	Proposed Re-evaluation Decision
TSMP	Toxic Substances Management Policy
USEPA	United States Environmental Protection Agency
UV	ultraviolet

Appendix I Additional Data Requirements

The following data are required as a condition of continued registration under Section 12 of the *Pest Control Products Act*. The registrants are required to provide these data or an acceptable scientific rationale within the timeline specified in the decision letter that will be sent to the registrant by the PMRA.

DACO 4.6.6 Dermal Sensitization Threshold Quantification
This study is required to identify a threshold for dermal sensitization risk assessment for dimethoxane treated materials such as latex-based paints and textiles.

DACO 5.2 Product use information
This includes information which describes the use of the product and human activity associated with its use, the amount of active handled per day, the typical and maximum volume of material produced at the facility per day and the type of personal protective equipment typically worn in industrial facilities and the facility engineering controls, as well the amount of dimethoxane in the final finished products (such as textiles).

DACO 5.14 Other studies
A study that determines how much dimethoxane ends up in textiles due to its use as a preservative of textile auxiliaries and the leaching of dimethoxane from textiles are required to assess dermal and incidental oral exposure potential.

Appendix II Registered Products Containing Dimethoxane as of 3 July 2013

Registration Number	Marketing Class	Registrant	Product Name	Formulation Type	Guarantee (%)
27039	Technical Grade Active Ingredient	ANGUS Chemical Company	BIOBAN DXN Technical	Solution	92%
24552	Commercial	Dow Chemical Canada Inc.	BIOBAN DXN-A	Solution	92%

Appendix III Summary of Endpoints Selected for Dimethoxane Risk Assessments by the United States Environmental Protection Agency

Exposure Scenario	Dose[1] (mg/kg bw/day)	Study	Target MOE[2]
Incidental Oral - Short and intermediate-term	NOAEL = 125 mg/kg bw/day	NTP 15 month rat study	Residential/Occupational MOE = 100
Dermal - all durations	NOAEL = 100 mg/kg bw/day	90-Day Dermal Toxicity - Rats	Residential/Occupational MOE = 100
Cancer	Suggestive evidence of carcinogenicity to humans; quantitative risk assessment not required.		

[1] NOAEL = no observed adverse effect level.

[2] MOE = margin of exposure, including 10 fold for inter-species variation, and 10 fold for intra-species variation.

Appendix IV Label Amendments for Products Containing Dimethoxane

The label amendments presented below do not include all label requirements for individual end-use products, such as first aid statements, disposal statements, precautionary statements and supplementary protective equipment. Information on labels of currently registered products should not be removed unless it contradicts the following label statements.

The labels of end-use products must be amended to include the following statements to further protect workers and the environment.

I) For the technical grade and end-use products containing dimethoxane, the following must be included on the primary panel of the label:

POTENTIAL SKIN SENSITIZER

II) For the end-use product containing dimethoxane, the following statements must be included in the section entitled **PRECAUTIONS**:

Potential skin sensitizer.

Wear long-sleeved shirt, long pants, and chemical-resistant gloves during handling, clean-up and repair activities.

III) The following statement must be included in the section entitled **DIRECTIONS FOR USE**:

DO NOT use this product in the production of materials that will come into contact with food.

DO NOT contaminate irrigation or drinking water supplies or aquatic habitats by cleaning of equipment or disposal of wastes.

DO NOT discharge effluents containing this product into sewer systems, lakes, streams, ponds, estuaries, oceans, and other waters.

References

A. Information Considered in the Chemistry Assessment

Studies/Information Submitted by Applicant/Registrant (Unpublished)

PMRA Document Number	Reference
1796139	DMF-AAS-2 Chemical and Physical Properties, Hydrolysis of Giv-Gard DXN, Corrosion Test Summary, DACO: 2.14.1, 2.14.10, 2.14.11, 2.14.12, 2.14.13, 2.14.14, 2.14.2, 2.14.3, 2.14.4, 2.14.5, 2.14.6, 2.14.7, 2.14.8, 2.14.9, 2.15, 2.16
1796132	DMF-AAS-2 Purity Analysis of Giv-Gard DXN and DXN Pure by Gas Chromatography, Certificate of Analysis, No Impurities of Toxicological Concern, DACO: 2.13.2, 2.13.3, 2.13.4 (Sub. No. 1998-1117).

B. Information Considered in the Human Health Assessment

Studies/Information Submitted by Applicant/Registrant (Unpublished)

1145506	Chemical Manufacturers Association Antimicrobial Exposure Assessment Study